

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.         | FILING DATE                         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------------------------------|----------------------|---------------------|------------------|
| 10/810,738              | 03/26/2004                          | Louis C. Haddad      | 59343US003          | 9703             |
|                         | 7590 04/09/200<br>IVE PROPERTIES CO | EXAMINER             |                     |                  |
| PO BOX 33427            | 7                                   | VENCI, DAVID J       |                     |                  |
| ST. PAUL, MN 55133-3427 |                                     |                      | ART UNIT            | PAPER NUMBER     |
|                         |                                     |                      | 1641                |                  |
|                         |                                     |                      |                     |                  |
| SHORTENED STATUTOR      | Y PERIOD OF RESPONSE                | NOTIFICATION DATE    | DELIVERY MODE       |                  |
| · 3 MOI                 | 3 MONTHS 04/09/2007 ELECTRONIC      |                      | RONIC               |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com LegalDocketing@mmm.com

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Application No.                                                                                                                                                   | Applicant(s)                                                               |  |  |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--|--|--|--|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                   |                                                                            |  |  |  |  |
| Office Action Summary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 10/810,738                                                                                                                                                        | HADDAD ET AL.                                                              |  |  |  |  |
| omoo nodon odiniidi y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Examiner                                                                                                                                                          | Art Unit                                                                   |  |  |  |  |
| The MAILING DATE of this communication app                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | David J. Venci                                                                                                                                                    | 1641                                                                       |  |  |  |  |
| Period for Reply                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | ears on the cover sheet with the t                                                                                                                                | correspondence address                                                     |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period was Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                   | •                                                                          |  |  |  |  |
| 1) Responsive to communication(s) filed on <u>Febru</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | uary 14, 2007.                                                                                                                                                    |                                                                            |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 3) Since this application is in condition for allowar                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | · · · · · · · · · · · · · · · · · · ·                                                                                                                             |                                                                            |  |  |  |  |
| closed in accordance with the practice under E                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | x parte Quayle, 1935 C.D. 11, 45                                                                                                                                  | 53 O.G. 213.                                                               |  |  |  |  |
| Disposition of Claims                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 4)⊠ Claim(s) <u>1-31</u> is/are pending in the application.                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 4a) Of the above claim(s) <u>14 and 16-31</u> is/are withdrawn from consideration.                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 5) Claim(s) is/are allowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 6)⊠ Claim(s) <u>1-13 and 15</u> is/are rejected.                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 7) Claim(s) is/are objected to.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 8) Claim(s) <u>1-31</u> are subject to restriction and/or e                                                                                                                                                                                                                                                                                                                                                                                                                                                               | election requirement.                                                                                                                                             |                                                                            |  |  |  |  |
| Application Papers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                   | ,                                                                          |  |  |  |  |
| 9)⊠ The specification is objected to by the Examine                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | r                                                                                                                                                                 |                                                                            |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                   |                                                                            |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                   |                                                                            |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                   |                                                                            |  |  |  |  |
| Priority under 35 U.S.C. § 119                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | ·                                                                                                                                                                 | •                                                                          |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | priority under 25 U.C.C. \$ 110/a                                                                                                                                 | ) (4) 02 (6)                                                               |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 1. ☐ Certified copies of the priority documents have been received.                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                   |                                                                            |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                   |                                                                            |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                   |                                                                            |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                   |                                                                            |  |  |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                   |                                                                            |  |  |  |  |
| Attachment(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                   |                                                                            |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                                                                                                                                                                                                                                                                                                                                                                                                                               | ate                                                                                                                                                               |                                                                            |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date: 09/23/05; 05/27/05; 05/27/05; 02/23/05; 03/23/05; 02/15/05; 01/17/05; 09/13/04  5) Notice of Informal Patent Application 6) Other:                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                   |                                                                            |  |  |  |  |

Art Unit: 1641

**DETAILED ACTION** 

Election/Restrictions

Examiner acknowledges Applicants' election of Invention I, claims 1-13 and 15, with traverse. Applicants

traversal appears premised, at least in part, on Applicants' knowledge of overlapping art and genuine

concern for Examiner's impending search burden. Applicants' concern for Examiner's well-being is well

taken and, as such, Examiner did not search for the particles, proteins and devices of Inventions II

through VIII. The requirement is considered proper and is made FINAL.

Claims 14 and 16-31 are directed to non-elected inventions. Herein, Examiner withdraws claims 14 and

16-31 from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected

inventions, there being no allowable generic or linking claim.

Information Disclosure Statement

The information disclosure statement filed September 13, 2004, fails to comply with 37 CFR 1.98(a)(2),

which requires a legible copy of each cited foreign patent document; each non-patent literature

publication or that portion which caused it to be listed; and all other information or that portion which

caused it to be listed. The information disclosure statement is in the application file, but the information

referred to in the 200+ references has not been considered.

Page 2

Art Unit: 1641

Specification

Page 3

The disclosure is objected to because of the following informalities:

On p. 8, lines 4-5, the phrase "the nonspecific binding of molecules (e.g., as in a target material)

to a solid phase material" lacks antecedent basis.

On p. 8, line 5, the identity of one or more prepositional reference objects of the phrase "in a

target material" is not clear.

On p. 8, line 5, the pronoun "which" is indefinite. The identity of one or more objects referenced

by "which" is not clear.

On p. 27, lines 19-20, the phrase "fabricated as described" is indefinite. The identity of one or

more locations in Applicants' specification referenced by "fabricated as described" is not clear.

On p. 29, line 1, the phrase "The polypropylene membrane[...] used in Example 3" (paraphrasing

mine) lacks antecedent basis.

Throughout Example 4, the identity of one or more objects referenced by the phrases "CHES

buffer" and "CHES/sulfate buffer" is not clear.

On p. 29, line 11, the pronoun "They" is indefinite. The identity of objects referenced by "They" is

not clear.

On p. 30, line 11, the phrase "was not eluted" is indefinite in view of Table 3, column 3, "EB"

Page 4

Art Unit: 1641

On p. 30, line 13, the pronoun "It" is indefinite. The identity of objects referenced by "It" is not clear.

On p. 31, line 4, the term "treatment" is indefinite because. The identity of one or more objects and/or steps required for "treatment" is not clear.

Appropriate correction is required.

Art Unit: 1641

Claim Rejections - 35 USC § 101

Section 101 of 35 U.S.C. reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

requirements of this title.

Claims 1-13 and 15 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and

therefore lacks utility.

Notwithstanding issues of indefiniteness, addressed infra, independent claims 1 and 15 are directed to

methods of "reducing" nonspecific binding of molecules to surfaces. Applicants assert their method is

useful for "reducing" nonspecific binding of molecules to a surface (see Title and Abstract), while

simultaneously "decreasing" the loss of molecules due to nonspecific binding to a solid phase (see

Specification, p. 2, lines 13-17).

According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is

based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic

underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion

of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicants' asserted utilities are premised on experiments that Applicants perform with a certain

proprietary composition (i.e., "NOVEC FC4432") that appears to increase binding of molecules to

surfaces. 1,2,3,4 In other words, Applicants' experiments appear to accomplish the exact opposite of

Applicants' stated intention.

<sup>1</sup> See e.g., Specification, Example 1, p. 25, first sentence, "Table 1 shows that using the nonionic polymeric fluorocarbon surfactant (NOVEC FC4432) resulted in a significantly higher recovery of the IgG" (emphasis mine).

See e.g., Specification, Example 2, p. 26, last sentence, "Table 2 shows that blocking with NOVEC FC4432 fluorosurfactant

significantly <u>increases</u> the recovery of the IgG" (emphasis mine).

<sup>3</sup> Examiner did not consider Example 3 because Applicants might have forgotten to add the Protein A.

Claim Rejections - 35 USC § 112 - first paragraph

Page 6

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode

contemplated by the inventor of carrying out his invention.

Claims 1-13 and 15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed

invention is not supported by either a credibly asserted utility or a well established utility for the reasons

set forth above, one skilled in the art clearly would not want to know how to use the claimed invention.

Claim Rejections - 35 USC § 112 - second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the

subject matter which the applicant regards as his invention.

Claims 1-13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

Claim 1 is incomplete for omitting essential steps, such omission amounting to a gap between the

steps. See MPEP § 2172.01. Specifically, the preamble does not correspond to the method

outcome because the identity of one or more objects and/or steps required for measuring "binding

of target molecules to a surface" are not clearly set forth and appear omitted. The identity of one

<sup>4</sup> Examiner did not consider Example 4 because Examiner made too many objections to this portion of the Specification.

or more standards for ascertaining or establishing a "reducing" or a reduction of "binding of target molecules to a surface", are not clearly set forth and appear omitted.

Claim 1 is incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Specifically, the body of claim 1 omits "a surface" as recited in the preamble.

Claim 1 is incomplete for omitting essential structural cooperative relationships between elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. Specifically, essential structural cooperative relationships between "a surface", "material", "portion" and "sites" are not clearly set forth and appear omitted.

Throughout the claim, the term "contacting" is indefinite because the identity of two or more objects subject to "contacting" is not clear. Furthermore:

The phrase "the solid phase material with the fluorinated nonionic surfactant" lacks antecedent basis.

The phrase "the solid phase material with the secondary blocking agent" lacks antecedent basis.

The phrase "the blocked solid phase material with the sample" lacks antecedent basis.

The phrase "contacting the blocked solid phase material" is indefinite wherein "optionally providing a secondary blocking agent" = FALSE.

Art Unit: 1641

The phrase "contacting the blocked solid phase material with the sample" is indefinite wherein

"optionally providing a secondary blocking agent" = FALSE.

The infinitive "to adhere" is indefinite. Whether the act or process of "adhering" is completed or

performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any,

required for performing "adhering" is not clear. Whether such an "adhering" step references the

anteceding "nonspecific binding" is not clear.

In claim 15:

Claim 15 is incomplete for omitting essential steps, such omission amounting to a gap between

the steps. See MPEP § 2172.01. Specifically, the preamble does not correspond to the method

outcome because the identity of one or more objects and/or steps required for measuring "binding

of molecules to a surface" are not clearly set forth and appear omitted. The identity of one or

more standards for ascertaining or establishing a "reducing" or a reduction of "binding of

molecules to a surface", are not clearly set forth and appear omitted.

Claim 1 is incomplete for omitting essential elements, such omission amounting to a gap between

the elements. See MPEP § 2172.01. Specifically, the body of claim 1 omits "molecules" and "a

surface" as recited in the preamble.

Claim 1 is incomplete for omitting essential structural cooperative relationships between

elements, such omission amounting to a gap between the necessary structural connections. See

MPEP § 2172.01. Specifically, essential structural cooperative relationships between "a surface",

"material", "portion" and "portion of the hydrophobic portion" are not clearly set forth and appear

omitted.

Art Unit: 1641

Throughout the claim, the term "contacting" is indefinite because the identity of two or more

objects subject to "contacting" is not clear. Furthermore:

The phrase "the solid phase material with the fluorinated nonionic surfactant" lacks

Page 9

antecedent basis.

The phrase "the solid phase material with the secondary blocking agent" lacks

antecedent basis.

The infinitive "to block" is indefinite. Whether the act or process of "blocking" is completed or

performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any,

required for performing "blocking" is not clear. Whether such a "blocking" step references the

anteceding "nonspecific binding" is not clear.

Art Unit: 1641

Page 10

Conclusion

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci Examiner Art Unit 1641

djv

LONG V. LE 3/30/3 SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600